- **Laboratory coagulation test interference**
  - Hemlibra affects assays for activated partial thromboplastin time (aPTT) and all assays based on aPTT, such as one stage factor VIII activity (see table 1 below).

  - Therefore, aPTT-based coagulation laboratory test results, in patients who have been treated with Hemlibra prophylaxis, should not be used to monitor Hemlibra activity, determine dosing for factor replacement or anti-coagulation, or measure factor VIII inhibitors titers. Misinterpretation of their results may lead to under-treatment of patients experiencing bleeding episodes, which can potentially result in severe or life-threatening bleeds.

  - However, single-factor assays utilising chromogenic or immuno-based methods are not affected by emicizumab and may be used to monitor coagulation parameters during treatment, with specific considerations for FVIII chromogenic activity assays.

  - Chromogenic factor VIII activity assays containing bovine coagulation factors are insensitive to emicizumab (no activity measured) and can be used to monitor endogenous or infused factor VIII activity, or to measure anti-FVIII inhibitors. A chromogenic Bethesda assay utilising a bovine-based factor VIII chromogenic test that is insensitive to emicizumab may be used.
  - Laboratory tests affected and unaffected by Hemlibra are shown in Table 1 below.
  - Due to the long half-life of Hemlibra, these effects on coagulation may persist for up to 6 months after last dose (see section 5.2 of the SmPC).

Table 1 Coagulation Test Results Affected and Unaffected by Hemlibra

Results Affected by Hemlibra
– Activated partial thromboplastin time (aPTT)
– Activated clotting time (ACT)
– One-stage, aPTT-based, single-factor assays
– aPTT-based Activated Protein C Resistance (APC-R)
– Bethesda assays (clotting-based) for FVIII inhibitor titers

Results Unaffected by Hemlibra
– Thrombin time (TT)
– One-stage, PT-based, single-factor assays
– Chromogenic-based single-factor assays other than FVIII[1]
– Immuno-based assays (e.g. ELISA, turbidometric methods)
– Bethesda assays (bovine chromogenic) for FVIII inhibitor titers
– Genetic tests of coagulation factors (e.g. Factor V Leiden, Prothrombin 20210)

[1]For important considerations regarding FVIII chromogenic activity assays, see section 4.4. of the SmPC.

Contact the patient's Haematologist listed above for assistance in interpreting laboratory test results or for **guidance on the use of bypassing agents in patients receiving Hemlibra prophylaxis.**

Or refer to the Patient Information Leaflet (PIL), SmPC and website at www.ema.europa.eu for additional information and guidance.

What additional important information should I know?

- Please read the Package Leaflet for further information.
- The side effects listed on this card are **not all** of the possible side effects that you could experience with Hemlibra.
- **Tell** your doctor, nurse or pharmacist about **any** side effect you experience, bothers you or that does not go away. This includes any possible side effects not listed in the Package Leaflet.
- **Talk** to your doctor, nurse or pharmacist if you have any questions, problems or for more information.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:
Post: The Drug Surveillance Centre, Roche Products (Ireland) Limited, 3030 Lake Drive, Citywest Business Campus, Dublin 24, D24 KX6Y, Ireland.

Telephone: 00 353 (1) 469 0700;
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at: http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:

Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta

Email: postlicensing.medicinesauthority@gov.mt

Company contact point

Contact:
Medical Information at Roche Products (Ireland) Limited by telephone (00353 1 4690700) or email (Ireland.druginfo@roche.com).

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

Roche

MT Version 4.7.1
Date of MMA Approval: June 2026

M-MT-00000029

FOR USE IN MALTA

Hemlibra (emicizumab): Patient Card

Patient Card for patients to ensure safe use of Hemlibra for treatment of Haemophilia A.

- This Patient Card describes recommendations to minimise or prevent important risks of the drug.
- See the Hemlibra Package Leaflet for more information on possible side effects of Hemlibra.

Please read this material along with the Patient/Carer Guide, and the Package Leaflet supplied with this medicine or also available on www.ema.europa.eu before taking this medicine.

Patients/caregivers should carry this Patient Card at all times including emergencies. Please present the card at visits to doctors, hospital clinics, laboratory professionals or pharmacists to provide information on emicizumab treatment and risks.

Please read this information carefully before administering the product.

Select Important Safety Information

- Serious and potentially life-threatening side effects have been observed when a "bypassing agent" called aPCC was used in patients who were also receiving Hemlibra. These included:
  - **Destruction of red blood cells (thrombotic microangiopathy (TMA))** – this is a serious and potentially life-threatening condition where there is damage to the lining of blood vessels and formation of blood clots in small blood vessels. This can lead to damage in the kidneys and/or other organs.
  - **Blood clots (thromboembolism)** – Blood clots may form and in rare cases these blood clots may cause a life-threatening blockage of blood vessels.
- Tell your doctor if you are using Hemlibra before you have laboratory tests that measure how well your blood is clotting. This is because the presence of Hemlibra in the blood may interfere with some of these laboratory tests, leading to inaccurate results.

In case of an emergency:

- Contact an appropriate medical professional for immediate medical care.

- Should any questions related to your haemophilia A or current treatment arise, please have them contact your doctor:

Name:.....

Tel/Fax:.....

Email:.....

[Your Haematologist's contact information]

Notice to health care professionals reading this Patient Card:

Please be aware of:

- **Thrombotic microangiopathy associated with Hemlibra and aPCC**
  - Cases of thrombotic microangiopathy (TMA) were reported from a clinical trial in patients receiving Hemlibra prophylaxis when on average a cumulative amount of >100U/kg/24 hours of activated prothrombin complex concentrate (aPCC) for 24 hours or more was administered.
  - Patients receiving Hemlibra prophylaxis should be monitored for the development of TMA when administering aPCC.
- **Thromboembolism associated with Hemlibra and aPCC**
  - Serious thrombotic events (TE) were reported from a clinical trial in patients receiving Hemlibra prophylaxis when on average a cumulative amount of >100U/kg/24 hours of activated prothrombin complex concentrate (aPCC) for 24 hours or more was administered.
  - Patients receiving Hemlibra prophylaxis should be monitored for the development of thromboembolism when administering aPCC.
- **Use of bypassing agents in patients receiving Hemlibra**
  - Treatment with prophylactic bypassing agents should be discontinued the day before starting Hemlibra therapy.
  - Physicians should discuss with all patients and/or caregivers the exact dose and schedule of bypassing agents to use, if required while receiving Hemlibra prophylaxis.
  - Hemlibra increases patients' coagulation potential. The bypassing agent dose required may therefore be lower than that used without Hemlibra prophylaxis. The dose and duration of treatment with bypassing agents will depend on the location and extent of bleeding, and the patient's clinical condition.
  - For all coagulation agents (aPCC, rFVIIa, FVIII, etc.), consideration should be given to verifying bleeds prior to repeated dosing.
  - Use of aPCC should be avoided unless no other treatment options/alternatives are available.
    - If aPCC is the only option to treat bleeding for a patient receiving Hemlibra prophylaxis, the initial dose should not exceed 50 U/kg and laboratory monitoring is recommended (including but not restricted to renal monitoring, platelet testing, and evaluation of thrombosis).
    - If bleeding is not controlled with the initial dose of aPCC up to 50 U/kg, additional aPCC doses should be administered under medical guidance or supervision, and the total aPCC dose should not exceed 100 U/kg in the first 24-hours of treatment.
    - Treating physicians must carefully weigh the risk of TMA and TE against the risk of bleeding when considering aPCC treatment beyond 100 U/kg in the first 24-hours.
  - The safety and efficacy of emicizumab has not been formally evaluated in the surgical setting. If patients require bypassing agents in the perioperative setting, it is recommended that the dosing guidance above for aPCC be followed by your doctor.
  - In clinical trials, no cases of TMA or TE were observed with use of activated recombinant human FVII (rFVIIa) alone in patients receiving Hemlibra prophylaxis; however, the lowest dose expected to achieve hemostasis should be prescribed. Caution should be used when treating patients who are at high risk for TMA (e.g. have a previous medical history or family history of TMA), or those who are receiving concomitant medicinal products known to be a risk factor for the development of TMA (e.g. ciclosporin, quinine, tacrolimus).
  - Due to the long half-life of Hemlibra, bypassing agent dosing guidance should be followed for at least 6 months following discontinuation of Hemlibra prophylaxis.
  - Please refer to section 4.4 of the SmPC for additional information and comprehensive instructions. The SmPC is available on www.ema.europa.eu.